

ISDH Long Term Care Newsletter Issue # 08-13 May 19, 2008

In Today's Issue:

- Heparin Recall Information

Good Morning,

The U.S. Food and Drug Administration (FDA) has requested the Indiana State Department of Health (ISDH) to disseminate information concerning the recall of selected Heparin products. Complete recall information of all products recalled is available on the <u>FDA Web site</u>. You are encouraged to review this information.

Below please find a letter from FDA concerning this recall. Thank you for your attention to this matter.

Terry Whitson
Assistant Commissioner
Indiana State Department of Health

FDA Heparin Recall Information

From: FDA NEWS FOR HEALTHCARE PROFESSIONALS [mailto:NewsHealthCareProfs@fda.hhs.gov]

Sent: Friday, May 09, 2008 8:39 AM

To: FDA NEWS FOR HEALTHCARE PROFESSIONALS

Subject: Heparin Update

Dear Colleague,

Please help the Food and Drug Administration (FDA) spread the word about recalls of injectable heparin products and heparin flush solutions that may be contaminated with oversulfated chondroitin sulfate (OSCS). Affected heparin products have been found in medical care facilities in one state since the recall announcement. Although product recall instructions were widely distributed, they may not have been fully acted upon at all sites where heparin is used. There have been many reports of deaths associated with allergic or hypotensive symptoms after heparin administration (see FDA link at http://www.fda.gov/cder/drug/infopage/heparin/adverse events.htm).

We ask that health professionals and facilities please review and examine all drug/device storage areas,

including emergency kits, dialysis units and automated drug storage cabinets to ensure that all of the recalled heparin products have been removed and are no longer available for patient use. In addition, FDA would like to inform health professionals about other types of medical devices that contain, or are coated with, heparin. To read this update, and to learn how to report these problems to FDA, please go to: http://www.fda.gov/cdrh/safety/heparin-healthcare-update.html. Please report to FDA adverse reactions associated with these devices, as well as any reactions associated with heparin or heparin flush solutions. If you have questions or would like more information about this request, please contact the Division of Drug Information at 301-796-3400.

We apologize in advance if you receive multiple copies of this information. Thank you for your ongoing support of FDA activities.

Sincerely,

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